UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 10, 2001

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 71661-R / Surfacine
DP Barcode: D273291
Case No: 070100

To: Adam Heyward, PM 34 / Renae Whitaker
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

5/10/01

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Intelligent Biocides, LLC

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Silver	0.0095
Poly(hexamethylenebiguanide) hydrochloride	0.56
Other Ingredient(s):	99.43
Total:	100.0000%

BACKGROUND: Intelligent Biocides, LLC, has submitted a "six-pack" of acute toxicity studies to support the registration of their new product "Surfacine® All-Purpose Cleaner". The studies were conducted by Product Safety Labs. The MRID Numbers are 453288-04 through 453288-09. These studies were reviewed for PSB/AD by the EPA contractor Oakridge Laboratories. A secondary review of the studies was conducted by PSB/AD.

RECOMMENDATIONS: PSB findings are:

Each of the six submitted studies is acceptable.

The acute toxicity profile for EPA File Symbol 71661-R is currently:

acute oral toxicity	IV	acceptable
acute dermal toxicity	IV	acceptable
acute inhalation toxicity	IV	acceptable
primary eye irritation	III	acceptable
primary skin irritation	IV	acceptable
dermal sensitization	nonsensitizer	acceptable

LABELING:

ID #: 071661-00001 Surfacine All-Purpose Cleaner

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

DATA EVALUATION RECORD

SURFACINE® ALL-PURPOSE CLEANER

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [870.1100 (§81-1)]
MRID 45328804

Prepared for
Antimicrobial Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K280

Primary Reviewer: Gary A. Sega, Ph.D.	Signature: Date:	Gary Sega MAY 0 3 2001
Secondary Reviewers: H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature: Date:	H T Borges MAY 0 3 2001
Robert H. Ross, M.S., Group Leader	Signature: Date:	Robert H. Ross MAY 0 3 2001
Quality Assurance: Lee Ann Wilson, M.A.	Signature: Date:	L. A. Wilson MAY 0 3 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Dept. of Energy under contract DE-AC05-00OR22725

EPA Reviewer: Ian Blackwell, M.S. Date: 5/10/01

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. Date: _____
Antimicrobial Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat [OPPTS 870.1100 (§81-1)]

DP BARCODE: D273291
P.C. CODE:

SUBMISSION CODE: S593644
CASE NO.: 070100

TEST MATERIAL: Surfacine® Cleaner Disinfectant
SYNONYMS: None reported

CITATION: Merkel, D. J. (2000) Acute oral toxicity study in rats - limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project ID: 8673, April 26, 2000. MRID 45328804. Unpublished.

SPONSOR: Intelligent Biocides, LLC, One Industrial Way, Tyngsboro, MA 01879

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 45328804) five male and five female fasted young adult Sprague-Dawley rats were given a single oral 5000 mg/kg dose of SURFACINE® (Batch No. 5006-23) and observed for 14 days.

No rats died during the study. All rats appeared normal and gained weight during the study. No visible lesions were noted at necropsy.

The oral LD_{50} for males, females, and combined was > 5000 mg/kg (Limit Test).

SURFACINE® is in TOXICITY CATEGORY IV based on the LD_{50}.

This acute oral study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute oral study [870.1100 (§81-1)] in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Surfacine® All-Purpose Cleaner

   Description: colorless, slightly hazy liquid
   Batch No.: 5006-23
   Composition:

Active ingredients: Polyhexamethylene biguanide hydrochloride (PHMB.HCl): 0.56%;
Silver (as the nitrate): 0.0095%
Other ingredients 99.4305%
EPA Chemical Codes: 72501 for $AgNO_3$; 111801for PHMB.HCl

2. Vehicle and/or positive control: None

3. Test animals:

Species: rat
Strain: Sprague-Dawley derived, albino
Age and weight at dosing: young adults; males: 204 - 210 g; females: 165 - 178 g
Source: Ace Animals, Inc., Boyertown, PA
Acclimation period: 9 days
Diet: Purina Rodent Chow #5012
Water: filtered tap water, *ad libitum*
Housing: singly housed in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 15-23 °C
Relative Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates

Start: January 20, 2000; end: February 3, 2000

2. Animal assignment and treatment:

The study was conducted as a limit test. Following a 16.5 hour fast, five rats/sex were given a single 5000 mg/kg dose of the test material by gavage. The animals were observed for clinical signs of toxicity at least once daily for 14 days. They were weighed prior to dosing and on study days 7 and 14. All rats were sacrificed and necropsied.

3. Statistics:

Calculation of the oral LD_{50} was not required.

II. RESULTS AND DISCUSSION

A. MORTALITY

None of the rats died as a result of SURFACINE® toxicity.

The oral LD_{50} for males, females, and combined was > 5000 mg/kg. This places SURFACINE® in TOXICITY CATEGORY IV.

B. CLINICAL OBSERVATIONS

All rats appeared normal throughout the study.

C. BODY WEIGHT

All rats gained weight during the study.

D. NECROPSY

No visible lesions were noted.

E. DEFICIENCIES

The relative humidity and the air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

SURFACINE® ALL-PURPOSE CLEANER

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT [870.1200 (§81-2)]
MRID 45328805

Prepared for
Antimicrobial Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K280

Primary Reviewer:
Gary A. Sega, Ph.D.

Signature: Gary Sega
Date: MAY 0 3 2001

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H T Borges
Date: MAY 0 3 2001

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: MAY 0 3 2001

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: MAY 0 3 2001

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Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Dept. of Energy under contract DE-AC05-00OR22725

EPA Reviewer: Ian Blackwell, M.S. Date: 5/16/01

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. Date: _____
Antimicrobial Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat [OPPTS 870.1200 (§81-2)]

DP BARCODE: D273291 SUBMISSION CODE: S593644
P.C. CODE: CASE NO.: 070100

TEST MATERIAL: Surfacine® Cleaner Disinfectant

SYNONYMS: None reported

CITATION: Merkel, D. J. (2000) Acute dermal toxicity study in rats - limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project ID: 8674, April 26, 2000. MRID 45328805. Unpublished.

SPONSOR: Intelligent Biocides, LLC, One Industrial Way, Tyngsboro, MA 01879

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 45328805) five male and five female fasted young adult Sprague-Dawley rats were given a single 5000 mg/kg dermal dose of SURFACINE® (Batch No. 5006-23) and observed for 14 days.

No rats died during the study. All rats appeared normal and gained weight during the study. No visible lesions were noted at necropsy.

The dermal LD_{50} for males, females, and combined was > 5000 mg/kg (Limit Test).

SURFACINE® is in TOXICITY CATEGORY IV based on the dermal LD_{50}.

This acute dermal study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute dermal toxicity study [870.1200 (§81-2)] in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Surfacine® All-Purpose Cleaner

Description: colorless, slightly hazy liquid
Batch No.: 5006-23
Composition:
Active ingredients: Polyhexamethylene biguanide hydrochloride (PHMB.HCl):
0.56%;
Silver (as the nitrate): 0.0095%
Other ingredients 99.4305%
EPA Chemical Codes: 72501 for $AgNO_3$; 111801for PHMB.HCl

2. Vehicle and/or positive control: None

3. Test animals

Species: rat
Strain: Sprague-Dawley derived, albino
Age and weight at dosing: young adults; males: 200 - 212 g; females: 162 - 199 g
Source: Ace Animals, Inc., Boyertown, PA
Acclimation period: 9 days
Diet: Purina Rodent Chow #5012
Water: filtered tap water, *ad libitum*
Housing: singly housed in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 15-23 °C
Relative Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates

Start: January 20, 2000; end: February 3, 2000

2. Animal assignment and treatment:

The study was conducted as a limit test using five male and five female rats given a single 5000 mg/kg dose of Surfacine® applied to the clipped dorsal area (approximately 10% of the body surface). The application site was covered with a gauze pad, then the gauze pad and entire trunk of each animal were wrapped with Durapore tape. After 24 hours, the pads were removed and the test sites gently wiped with water and a clean towel to remove any residual substance. The animals were observed for mortality, signs of gross toxicity and behavioral changes 1 and 6.5 hours after treatment and at least once daily thereafter for 14 days. They were weighed prior to test material application, and on study days 7 and 14. All rats were sacrificed and necropsied on day 14.

3. Statistics

Calculation of the dermal LD_{50} was not required.

II. RESULTS AND DISCUSSION

A. MORTALITY

None of the rats died as a result of SURFACINE® toxicity.

The dermal LD_{50} for males, females, and combined was > 5000 mg/kg. This places SURFACINE® in TOXICITY CATEGORY IV.

B. CLINICAL OBSERVATIONS

All rats appeared active and healthy throughout the study.

C. BODY WEIGHT

All rats gained weight during the study.

D. NECROPSY

No visible lesions were noted.

E. DEFICIENCIES

The relative humidity and the air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

SURFACINE® ALL-PURPOSE CLEANER

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT [870.1300 (§81-3)]
MRID 45328806

Prepared for
Antimicrobial Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K280

Primary Reviewer: Gary A. Sega, Ph.D.	Signature: Date:	Gary Sega MAY 0 3 2001
Secondary Reviewers: H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature: Date:	H T Borges MAY 0 3 2001
Robert H. Ross, M.S., Group Leader	Signature: Date:	Robert H. Ross MAY 0 3 2001
Quality Assurance: Lee Ann Wilson, M.A.	Signature: Date:	L. A. Wilson MAY 0 3 2001

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Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Dept. of Energy under contract DE-AC05-00OR22725

EPA Reviewer: Ian Blackwell, M.S. Date: 5/10/01

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. Date: _____
Antimicrobial Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Acute Inhalation Toxicity - Rat [OPPTS 870.1300 (§81-3)]

DP BARCODE: D273291 SUBMISSION CODE: S593644
P.C. CODE: CASE NO.: 070100

TEST MATERIAL: Surfacine® Cleaner Disinfectant

SYNONYMS: None reported

CITATION: Merkel, D. J. (2000) Acute inhalation toxicity study in rats - limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project ID: 8675, April 26, 2000. MRID 45328806. Unpublished.

SPONSOR: Intelligent Biocides, LLC, One Industrial Way, Tyngsboro, MA 01879

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 45328806) five male and five female young adult Sprague-Dawley rats were exposed to an aerosol of SURFACINE® (Batch No. 5006-23) for 4 hours at an average concentration of 2.11 mg/L and observed for 14 days.

No rats died during the study. Some clinical signs were noted during exposure and after exposure for up to 3 days. All animals recovered beyond 3 days and remained healthy throughout the remainder of the study. All rats gained weight during the study. No visible lesions were noted at necropsy.

The inhalation LC_{50} for males, females, and combined was > 2.11 mg/L (Limit Test).

SURFACINE® is in TOXICITY CATEGORY IV based on the LC_{50}.

This acute inhalation study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute inhalation study [870.1300 (§81-3)] in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Surfacine® All-Purpose Cleaner

Description: colorless, slightly hazy liquid
Batch No.: 5006-23
Composition:
Active ingredients: Polyhexamethylene biguanide hydrochloride (PHMB.HCl):
0.56%;
Silver (as the nitrate): 0.0095%
Other ingredients 99.4305%
EPA Chemical Codes: 72501 for $AgNO_3$; 111801for PHMB.HCl

2. Vehicle and/or positive control: None

3. Test animals:

Species: rat
Strain: Sprague-Dawley derived, albino
Age and weight at dosing: young adults; males: 222 - 249 g; females: 174 - 209 g
Source: Ace Animals, Inc., Boyertown, PA
Acclimation period: 9 days
Diet: Purina Rodent Chow #5012
Water: filtered tap water, *ad libitum*
Housing: singly housed in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 15-23 °C
Relative Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates

Start: January 27, 2000; end: February 10, 2000

2. Exposure conditions

Temperature and humidity were recorded every 15 minutes for the first hour of exposure and every 30 minutes thereafter. The temperature and relative humidity ranges during exposure were 19 - 21°C and 30 - 78% RH, respectively.

3. Animal assignment and treatment:

The study was conducted as a limit test. Animals were assigned to the test groups noted in Table 1. Rats were exposed to Surfacine® for 4 hours and 15 minutes. The animals were observed at least every 30 minutes during exposure and after exposure excess test material was removed from the fur. The animals were observed at least once daily thereafter for 14 days. They were weighed prior to test material exposure and again on day 7 and 14. All rats were sacrificed and necropsied on day 14.

TABLE 1. Concentrations, exposure conditions, mortality/animals treated

Nominal Conc. (mg/L)	Grav. Conc. (mg/L)	MMAD (µm)	GSD (µm)	Particles ≤ 4.7 µm (%)	Temp. (°C)	Humidity (%)	Male	Female	Combined
28.49	2.11	2.4–2.5	1.84–1.94	83.8–86.6	19–21	30–78	0/5	0/5	0/10

4. Generation of the test atmosphere and description of the chamber

The exposure atmosphere was generated using a 1/4 inch jet air atomizer. Compressed air coming to the atomizer was supplied at 30 psi and the test material was supplied to the atomizer from a peristaltic pump. The average total airflow was 45.7 liters/min and the whole body plexiglass exposure chamber had a volume of 150 L.

Time to 90 and 99% equilibrium was 7.5 and 15.1 minutes, respectively.

Analytical chemistry – None

Test atmosphere concentration - Gravimetric samples were collected using glass fiber filters from the breathing zone of the animals 6 times during exposure. The filters were weighed before and after collection to determine the mass collected. The value was divided by the total volume of air sampled to determine the chamber concentration. The average results are in Table 1 above.

Particle size determination - The particle size of the test material in the atmosphere was measured at two time intervals during exposure. Particle size was determined using an eight-stage Andersen cascade impactor. The test material concentration collected by each stage was determined gravimetrically. The aerodynamic mass median diameter and the geometric standard deviation were determined graphically using two-cycle logarithmic probit axes. Results are in Table 1 above.

5. Statistics

Calculation of the inhalation LC_{50} was not required.

II. RESULTS AND DISCUSSION

A. MORTALITY

No rats died as a result of inhalation toxicity from SURFACINE®.

The inhalation LC_{50} (4-hour exposure) for males, females, and combined was > 2.11 mg/L. This places SURFACINE® in TOXICITY CATEGORY IV for inhalation exposure.

B. CLINICAL OBSERVATIONS

In-chamber observations included ocular and nasal discharge, irregular respiration, hunched posture and hypoactivity. Upon removal from the chamber, irregular respiration, hunched posture and hypoactivity persisted and one rat exhibited a reduced fecal volume. All animals recovered fully by day 4 and remained healthy for the remainder of the study.

C. BODY WEIGHT

All rats gained weight during the study.

D. NECROPSY

No gross abnormalities were noted.

E. DEFICIENCIES

The relative humidity and the air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

SURFACINE® ALL-PURPOSE CLEANER

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT [870.2400 (§81-4)]
MRID 45328807

Prepared for
Antimicrobial Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K280

Primary Reviewer: Gary A. Sega, Ph.D.	Signature: Date:	Gary Sega MAY 0 3 2001
Secondary Reviewers: H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature: Date:	H T Borges MAY 0 3 2001
Robert H. Ross, M.S., Group Leader	Signature: Date:	Robert H. Ross MAY 0 3 2001
Quality Assurance: Lee Ann Wilson, M.A.	Signature: Date:	L. A. Wilson MAY 0 3 2001

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Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Dept. of Energy under contract DE-AC05-00OR22725

EPA Reviewer: Ian Blackwell, M.S. Date: 5/10/01

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. Date: _____
Antimicrobial Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit [OPPTS 870.2400 (§81-4)]

DP BARCODE: D273291 SUBMISSION CODE: S593644
P.C. CODE: CASE NO.: 070100

TEST MATERIAL: Surfacine® Cleaner Disinfectant

SYNONYMS: None reported

CITATION: Merkel, D. J. (2000) Primary eye irritation study in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project ID: 8676, April 26, 2000. MRID 45328807. Unpublished.

SPONSOR: Intelligent Biocides, LLC, One Industrial Way, Tyngsboro, MA 01879

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 45328807) 0.1 mL of Surfacine® (Batch #: 5006-23) was instilled into the right conjunctival sac of three male and three female New Zealand albino rabbits. The contralateral eye of all rabbits served as control. The eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation.

No corneal opacity or iritis were found on any rabbit. Conjunctival irritation was observed and this cleared from all treated eyes by 72 hours.

In this study, Surfacine® was mildly irritating to the rabbit eye and is in TOXICITY CATEGORY III for primary eye irritation.

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a primary eye irritation study [870.2400 (§81-4)] in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Surfacine® All-Purpose Cleaner

   Description: colorless, slightly hazy liquid

Batch No.: 5006-23
Composition:
Active ingredients: Polyhexamethylene biguanide hydrochloride (PHMB.HCl): 0.56%;
Silver (as the nitrate): 0.0095%
Other ingredients 99.4305%
EPA Chemical Codes: 72501 for $AgNO_3$; 111801for PHMB.HCl

2. Vehicle and/or positive control: None

3. Test animals

Species: rabbit
Strain: New Zealand albino
Age and weight at dosing: adult, 3 males and 3 females; weights not reported
Source: Davidson's Mill Farm, South Brunswick, NJ
Acclimation period: 7 days
Diet: Pelleted Purina Rabbit Chow #5326
Water: filtered tap water, *ad libitum*
Housing: singly housed in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 17-24 °C
Relative Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates

Start: January 28, 2000; end: January 31, 2000

2. Animal assignment and treatment:

The test material (0.1 mL) was instilled into the conjunctival sac of the right eye of three male and three female rabbits and the eye lids held together for approximately 1 second. The contralateral eye of each rabbit was untreated and served as control. Ocular irritation was evaluated using a high-intensity white light according to the Draize method at 1, 24, 48, and 72 hours post-instillation. Sodium fluorescein examinations were used to aid the examination at 24 hours and to verify the absence of corneal damage.

II. RESULTS AND DISCUSSION

A. No corneal opacity or iritis were found during the study. One hour after instillation of the test material, all treated eyes showed slight to mild conjunctivitis. The incidence and severity of irritation decreased thereafter, and all animals were free

from ocular irritation by 72 hours. The Draize scores for conjunctivitis during the study are shown in Table 1.

TABLE 1 Draize scores for conjunctivae after instillation of Surfacine®

	Male 746				Male 748				Male 750			
	Hours				Hours				Hours			
	1	24	48	72	1	24	48	72	1	24	48	72
A. Redness	2	2	2	0	2	2	2	0	2	2	2	0
B. Chemosis	1	1	1	0	1	1	1	0	1	1	1	0
C. Discharge	2	0	0	0	2	1	0	0	2	1	0	0
(A+B+C)x2	10	6	6	0	10	8	6	0	10	8	6	0
	Female 747				Female 749				Female 751			
	Hours				Hours				Hours			
	1	24	48	72	1	24	48	72	1	24	48	72
A. Redness	2	2	2	0	2	2	2	0	2	2	2	0
B. Chemosis	1	1	1	0	1	1	1	0	1	1	1	0
C. Discharge	2	0	0	0	2	1	1	0	2	1	0	0
(A+B+C)x2	10	6	6	0	10	8	8	0	10	8	6	0

Data taken from Table 1, pp. 11-12, MRID 45328807

The maximum average ocular irritation score was 10, recorded 1 hour after instillation. This classifies Surfacine® as mildly irritating to the eye and the TOXICITY CATEGORY is III.

B. DEFICIENCIES

The animal weights, relative humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

SURFACINE® ALL-PURPOSE CLEANER

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT [870.2500 (§81-5)]
MRID 45328808

Prepared for
Antimicrobial Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K280

Primary Reviewer: Gary A. Sega, Ph.D.	Signature: Date:	Gary Sega MAY 0 3 2001
Secondary Reviewers: H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature: Date:	HT Borges MAY 0 3 2001
Robert H. Ross, M.S., Group Leader	Signature: Date:	Robert H. Ross MAY 0 3 2001
Quality Assurance: Lee Ann Wilson, M.A.	Signature: Date:	L. A. Wilson MAY 0 3 2001

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Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Dept. of Energy under contract DE-AC05-00OR22725

EPA Reviewer: Ian Blackwell, M.S. Date: 5/10/01

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. Date: _____
Antimicrobial Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit [OPPTS 870.2500 (§81-5)]

DP BARCODE: D273291 SUBMISSION CODE: S593644
P.C. CODE: CASE NO.: 070100

TEST MATERIAL: Surfacine® Cleaner Disinfectant

SYNONYMS: None reported

CITATION: Merkel, D. J. (2000) Primary skin irritation study in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project ID: 8677, April 26, 2000. MRID 45328808. Unpublished.

SPONSOR: Intelligent Biocides, LLC, One Industrial Way, Tyngsboro, MA 01879

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 45328808) three male and three female adult New Zealand white rabbits were dermally exposed on the back to 0.5 mL Surfacine®(Batch #: 5006-23) for 4 hours. The animals were observed for 72 hours. Irritation was scored by the method of Draize.

One hour after patch removal, very slight erythema and edema was observed on all six treated sites. The overall incidence and severity of irritation decreased with time and all animals were free of dermal irritation by 48 hours. The primary dermal irritation index was 0.5.

In this study, Surfacine® was classified as slightly irritating. The TOXICITY CATEGORY is IV for primary dermal irritation.

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a primary dermal irritation study [870.2500 (§81-5)] in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Surfacine® All-Purpose Cleaner

Description: colorless, slightly hazy liquid
Batch No.: 5006-23
Composition:
Active ingredients: Polyhexamethylene biguanide hydrochloride (PHMB.HCl): 0.56%;
Silver (as the nitrate): 0.0095%
Other ingredients 99.4305%
EPA Chemical Codes: 72501 for $AgNO_3$; 111801for PHMB.HCl

2. Vehicle and/or positive control: None

3. Test animals

Species: rabbit
Strain: New Zealand albino
Age and weight at dosing: adult, 3 males and 3 females; weights not reported
Source: Davidson's Mill Farm, South Brunswick, NJ
Acclimation period: 12 days
Diet: Pelleted Purina Rabbit Chow #5326
Water: filtered tap water, *ad libitum*
Housing: singly housed in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 18-21 °C
Relative Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates

Start: January 19, 2000; end: January 22, 2000

2. Animal assignment and treatment:

Three males and three female rabbits were given a single 0.5 mL dose of Surfacine® applied to a 6 cm^2 clipped site on the back. The application site was covered with a gauze patch and secured with semi-occlusive 3 inch Micropore tape. Collars were also placed on each rabbit. After 4 hours of exposure, the gauze and collars were removed and the test sites gently wiped with water and a clean towel. The treated sites were scored for erythema and edema according to the Draize method at approximately 1, 24, 48, and 72 hours after patch removal.

II. RESULTS AND DISCUSSION

A. One hour after patch removal, very slight erythema and edema were observed on all six treated sites. The overall incidence and severity of irritation decreased with

time and all animals were free of dermal irritation by 48 hours. The primary dermal irritation index was 0.5

Surfacine® was classified as slightly irritating to skin. The TOXICITY CATEGORY is IV.

B. DEFICIENCIES

The animal weights, relative humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

SURFACINE® ALL-PURPOSE CLEANER

STUDY TYPE: DERMAL SENSITIZATION - GUINEA PIG [870.2600 (§81-6)]
MRID 45328809

Prepared for
Antimicrobial Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
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Action No. K280

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Dept. of Energy under contract DE-AC05-00OR22725

EPA Reviewer: Ian Blackwell, M.S. Date: 5/10/01

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. Date: _____
Antimicrobial Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Dermal Sensitization - Guinea Pig [OPPTS 870.2600 (§81-6)]
DP BARCODE: D273291 SUBMISSION CODE: S593644
P.C. CODE: CASE NO.: 070100

TEST MATERIAL: Surfacine® Cleaner Disinfectant

SYNONYMS: None reported

CITATION: Merkel, D. J. (2000) Dermal sensitization study in guinea pigs. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project ID: 8678, April 26, 2000. MRID 45328809. Unpublished.

SPONSOR: Intelligent Biocides, LLC, One Industrial Way, Tyngsboro, MA 01879

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 45328809) with Surfacine® (Batch #: 5006-23), 30 young adult male and female Hartley albino guinea pigs were tested using the Buehler method.

No dermal irritation consistent with sensitization was observed 24 and 48 hours after challenge with the test material. The study report included a DNCB positive control study which was carried out within six months of the current study. The results were appropriate.

Based on the evaluation system used in this study, Surfacine® was not a dermal sensitizer.

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a dermal sensitization study [870.2600 (§81-6)] in the guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Surfacine® All-Purpose Cleaner

Description: colorless, slightly hazy liquid
Batch No.: 5006-23
Composition:
Active ingredients: Polyhexamethylene biguanide hydrochloride (PHMB.HCl): 0.56%;
Silver (as the nitrate): 0.0095%
Other ingredients 99.4305%
EPA Chemical Codes: 72501 for $AgNO_3$; 111801for PHMB.HCl

2. Vehicle and/or positive control

No vehicle; positive control: 1-chloro-2,4-dinitrobenzene (DNCB) (historical data)

3. Test animals

Species: guinea pig
Strain: Hartley albino
Age and weight at dosing: young adults; males 290 - 357 g; females 298 - 364 g
Source: Davidson's Mill Farm, South Brunswick, NJ
Acclimation period: 5 days
Diet: Pelleted Purina Guinea Pig Chow #5025
Water: filtered tap water, *ad libitum*
Housing: group housed in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 14-25 °C
Relative Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates:

Start: January 19, 2000; end: February 17, 2000

2. Animal assignment and treatment

The animals were induced and challenged according to the Buehler method.

Induction phase: There were initially twenty animals in the test group. Once each week for three weeks, 0.4 ml of the pure test material was applied to the clipped left side of each test animal using an occlusive 25 mm Hilltop Chamber® that was held in place with non-allergenic adhesive tape. After a 6-hour exposure the Chambers were removed and the test sites gently wiped with water and a clean towel. At 24 and 48 hours after each induction application, local reaction (erythema) was recorded.

Challenge phase:Fourteen days after the last induction dose, a challenge dose was applied to the right side of each test animal using the same procedure used for the induction phase. The sites were evaluated 24 and 48 hours post exposure.

In addition to test animals, 10 guinea pigs from the same shipment were maintained under identical environmental conditions and were treated with the pure test material at challenge only. These animals constituted the naïve control group. One animal from this group died before the challenge phase.

II. RESULTS AND DISCUSSION

A. INDUCTION REACTIONS AND DURATION

Very faint erythema (score = 0.5) was noted at several test sites and at various intervals. One animal was found moribund before the second induction phase and was euthanized. The morbidity did not appear to be related to the treatment.

B. CHALLENGE REACTIONS AND DURATION

Test animals: Very faint erythema (score = 0.5) was noted at 5 test sites 24 hours after challenge. Irritation persisted at 2 of the affected sites through 48 hours. No irritation consistent with a sensitization response was observed.

Naive control animals: Very faint erythema was noted at 2 test sites 24 hours after challenge. Irritation persisted at one of the affected sites through 48 hours.

C. POSITIVE CONTROL

The study report included a DNCB positive control study which was carried out within six months of the current study. The results were appropriate.

D. ADDITIONAL TESTING

It is the reviewer's opinion that the study was conducted in a manner suitable to detect the sensitization potential of the test material. No additional testing is needed.

E. DEFICIENCIES

The relative humidity and air changes were not reported. It is unlikely that these parameters would have affected the study results.